

REMARKS/ARGUMENTS

Claims 1-6 and 50-62 are pending in the application. Claims 1-6 and 50-62 are rejected. Claims 7-49 have been canceled without prejudice to subsequent revival. Applicants reserve the right to prosecute claims 7-49 in a divisional application.

Claims 1, 6, 50 and 52-62 have been amended. Claims 63-94 have been added. Entry of the amendment, reconsideration of the rejection, and allowance of claims 1-6 and 50-94 are respectfully requested.

The Amendment

In order to expedite prosecution of the application and advance the case toward allowance, claims 1, 6, 50 and 52-62 has been amended. No new matter was added by the amendment.

Claim 1 has been amended to specify that the apparatus comprises "at least one" detection mechanism for measuring at least one signal. Support for this amendment can be found on page 9, lines 25-26. Claim 1 has further been amended to clarify that step (iv) refers to "the threshold" cycle number. Support for this amendment can be found on page 7, line 6 of the specification.

Claim 6 has been amended to specify that step (ii) calculates the "threshold" cycle number. Support for this amendment can be found on page 7, lines 28-30 of the specification.

Claim 50 has been amended to clarify that step (iii) refers to "the threshold" cycle number associated with a characteristic of the derivative. Support for this amendment can be found on page 10, lines 10-11 of the specification.

Claims 52-62 have been amended to specify that the cycle number is the "threshold" cycle number. Support for this amendment can be found on page 10, lines 10-11 and throughout the specification.

Claims 63-94 have been added. Support for these new claims can be found on page 7, lines 14-19; page 62, lines 18-34; and in the operation section beginning on page 63.

Rejections under 35 U.S.C. §103

Claims 1-6 and 50-62 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious over Haff *et al.* (U.S. Patent No. 5,827,480) in view of the legal decision of *in re Gulack*¹.

The Office Action appears to suggest that the language "wherein the controller is programmed to perform the steps of" does not further limit the structure of the apparatus and is to be given no consideration in determining whether or not the apparatus is distinguishable over the prior art.

To the extent that the rejection applies to claims as amended, Applicants respectfully traverse the rejection.

It is submitted that the program is indeed part of the apparatus. An apparatus with a controller programmed in a manner different from the one recited in the instant invention would be a different apparatus. As stated in the MPEP²: "If a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product." The MPEP further states that: "Office personnel must treat each claim as a whole." While these cases are directed primarily to the issue of whether claims including computer programs constitute statutory subject matter, the analysis is premised upon the paradigm that the computer program is a component of the claim. Similarly, the computer programmed controller is part of the apparatus and, thus, a component of the claim.

Applicants submit that claims 1-6 are patentable over Haff *et al.* because Haff *et al.* do not teach or suggest a controller programmed to perform the steps of:

- i) deriving a growth curve from the measurements of the signal;
- ii) calculating a derivative of the growth curve;
- iii) identifying a characteristic of the derivative; and
- iv) determining the threshold cycle number associated with the characteristic of the derivative.

¹ 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

² MPEP 2106; section IV; 2. Statutory Subject Matter; (a) Statutory Product Claims



Appl. No. 10/027,404
Amdt. dated February 4, 2004
Reply to Office Action of August 4, 2003

PATENT

Applicants further submit that claims 50-62 are patentable over Haff *et al.* because Haff *et al.* do not teach or suggest a controller programmed to perform the steps of:

- i) storing signal values defining a growth curve for the nucleic acid sequence, wherein the growth curve expresses signal intensity as a function of cycle number in the reaction;
- ii) determining a derivative of the growth curve, wherein the derivative is determined with respect to cycle number; and
- iii) calculating the threshold cycle number associated with a characteristic of the derivative.

In light of the above amendment and remarks, Applicants respectfully request that the rejection of claims 1-6 and 50-62 under 35 U.S.C. §103 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

Brigitte A. Hajos
Reg. No. 50,971

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
Attachments
BAH:bah
60134765 v1